PCT WORLD INTELLECTUAL PROPERTY ORGANIZATION
International Bureau

INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 6 : A61B 17/56	A1	(11) International Publication Number: WO 97/14366
		(43) International Publication Date: 24 April 1997 (24.04.97)

(21) International Application Number: PCT/US96/17283

(22) International Filing Date: 16 October 1996 (16.10.96)

(30) Priority Data:
08/544,884 18 October 1995 (18.10.95) US

(71) Applicant: CROSS MEDICAL PRODUCTS, INC. [US/US]; Suite A, 5160-A Blazer Memorial Parkway, Dublin, OH 43017-1339 (US).

(72) Inventor: MELLINGER, Philip, A.; 1094 Kirk Avenue, Worthington, OH 43085 (US).

(74) Agents: SHUNK, Laura, F. et al.; Hudak & Shunk Co., L.P.A., Suite 808, 7 West Bowery Street, Akron, OH 44308-1133 (US).

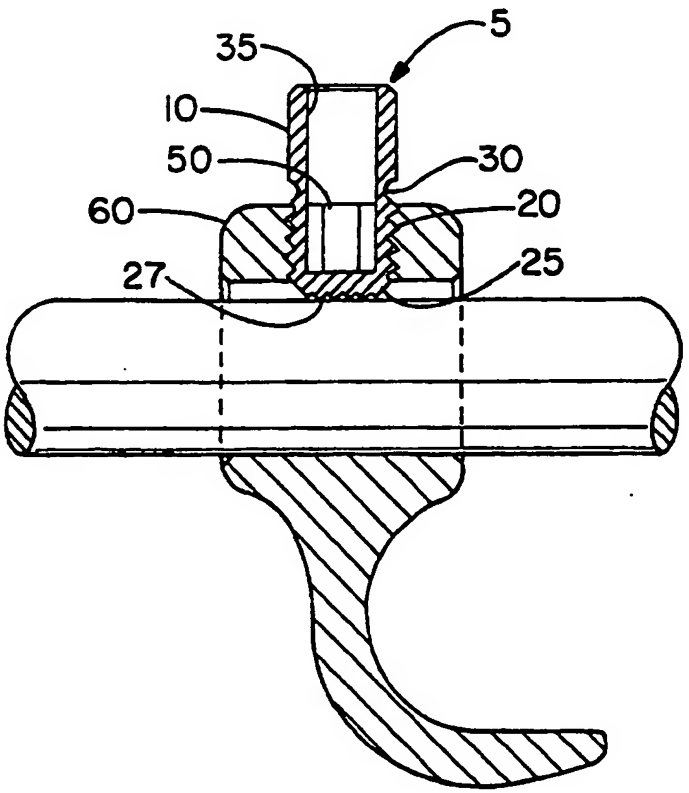
(81) Designated States: AU, BR, CA, HU, JP, KR, MX, SG, TR, European patent (AT, BE, CH, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE).

Published
With international search report.

(54) Title: SELF-LIMITING SET SCREW FOR USE WITH SPINAL IMPLANT SYSTEMS

(57) Abstract

The invention relates to a set screw (5) having a self-limiting external torque head (10). The head has a hexagonal external cross section and an internal bore (35) which extends through a necked portion (30). The necked portion joins the external torque head to the threaded screw portion (20) of the set screw. The necked portion has a cross-sectional thickness and strength to provide for shearing at a perdetermined load limit, such as from about 54 pounds per inch to about 64 pounds per inch. The threaded screw portion has an internal hex (50) to allow for the internal application of loosening torque at about two thirds of the tightening torque limit, i.e., to provide a loosening torque of about 40 pounds per inch. The screw member includes a high compression, rod contacting surface such as a knurled surface (27).



FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AM	Armenia	GB	United Kingdom	MW	Malawi
AT	Austria	GE	Georgia	MX	Mexico
AU	Australia	GN	Guinea	NE	Niger
BB	Barbados	GR	Greece	NL	Netherlands
BE	Belgium	HU	Hungary	NO	Norway
BF	Burkina Faso	IE	Ireland	NZ	New Zealand
BG	Bulgaria	IT	Italy	PL	Poland
BJ	Benin	JP	Japan	PT	Portugal
BR	Brazil	KE	Kenya	RO	Romania
BY	Belarus	KG	Kyrgystan	RU	Russian Federation
CA	Canada	KP	Democratic People's Republic of Korea	SD	Sudan
CF	Central African Republic			SE	Sweden
CG	Congo	KR	Republic of Korea	SG	Singapore
CH	Switzerland	KZ	Kazakhstan	SI	Slovenia
CI	Côte d'Ivoire	LI	Liechtenstein	SK	Slovakia
CM	Cameroon	LK	Sri Lanka	SN	Senegal
CN	China	LR	Liberia	SZ	Swaziland
CS	Czechoslovakia	LT	Lithuania	TD	Chad
CZ	Czech Republic	LU	Luxembourg	TG	Togo
DE	Germany	LV	Latvia	TJ	Tajikistan
DK	Denmark	MC	Monaco	TT	Trinidad and Tobago
EE	Estonia	MD	Republic of Moldova	UA	Ukraine
ES	Spain	MG	Madagascar	UG	Uganda
FI	Finland	ML	Mali	US	United States of America
FR	France	MN	Mongolia	UZ	Uzbekistan

SELF-LIMITING SET SCREW FOR USE WITH SPINAL IMPLANT SYSTEMS

FIELD OF THE INVENTION

The invention relates generally to set screws for use with spinal implant systems, and more particularly to a set screw having a head for the external application of torque which will shear at a predetermined load. The set screw further includes an internal opening for receiving a tool to permit the set screw to be removed.

BACKGROUND OF THE INVENTION

Spinal implant systems are used to strengthen, stabilize, and align the spine. Such systems often currently include an elongate stabilizer, such as a rod or plate; means to anchor the rod to a vertebra, such as a rod anchor, screw, or hook; and means to apply compression to the rod in order to hold it in place relative to the anchor. These compression means include external compression members (nuts or caps) and internal compression members (set screws or plugs).

Set screws are often used with various components of these systems to secure the components in position relative to one another. For example, the rod anchor may include a cap which twists or slides into position wherein a set screw is used to apply a compressive gripping force on the rod to hold it in position relative to the anchor. Some spinal systems include a closed anchor which encircles the rod wherein the set screw is used to lock the rod into position relative to the anchor. Set screws are also used to lock adjustable transverse links into position, and to lock the position of transversely adjustable rod-anchoring members.

Spinal implant systems are designed with the object of being able to apply and withstand relatively high mechanical forces so as to hold the spine in alignment while fusion takes place. However, it is also an object to provide a design which is as small as possible to provide minimal disruption to the biological environ-

ment. On the other hand, implant systems are designed with the goal of quick and efficient implantation during surgery. Therefore, the implant components need to be easy to assemble and large enough to enable the surgeon to easily handle them. Also the components need to interface well with the instrumentation to facilitate implantation and assembly during surgery.

Conventional prior art set screws require the use of a torque wrench to measure the amount of torque applied to the screw during assembly of the spinal implant system to assure that the set screw is engaged in the anchor tightly enough to hold the stabilizer securely in place relative to the anchor. If the surgeon overtightens the set screw, there is a risk of stripping the threads from the set screw; however, if the set screw is not tightened enough, the anchor may not have sufficient compressive grip on the stabilizer to enable the system to function properly.

The present invention therefore has an object of providing a set screw of a size which can be conveniently handled by the surgical staff during surgical implantation and which can be tightened to proper tightness without requiring the use of a torque wrench.

The invention has the further object of providing a means for the screw to be removed even after the head has been sheared from the screw. Therefore, the set screw in accordance with the present invention enables a surgeon to apply from about 50 to about 70 inch-pounds (6-8 Newton-meters) of torque to tighten the screw prior to the self-limiting shearing of the head at a preset maximum torque value. The set screw enables from about 35 to about 50 inch-pounds of loosening torque.

BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 is a side view of the set screw in accordance with the invention;

Figure 2 is a top view of the set screw;

Figure 3 is a bottom view of the set screw;

Figure 4 is a cross-section of the set screw of the invention taken generally along line 4-4 of Figure 2;

Figure 5 is a view of the set screw in a rod anchor prior to shearing of the external torque-receiving head; and

Figure 6 is a view of the rod anchor and set screw after shearing.

DETAILED DESCRIPTION OF INVENTION

A set screw 5 in accordance with the invention is shown in Figure 1 having a first externally threaded screw portion 20 and an axially aligned external torque or tightening head 10 joined to the screw portion 20 by a necked shearing area 30. By "external torque head" it is meant that the tightening torque is applied to the external surfaces of the head.

The torque head 10 has a shape and size which facilitates handling by the surgeon and which enables the external application of torque to tighten the set screw relative to a rod anchor (shown at 60 in Figures 5 and 6). Suitable cross-sectional shapes include triangular, square, pentagonal, hexagonal, octagonal, cross-shaped, and irregularly shaped configurations which would allow the transmission of a torquing force to the screw 5 to tighten it in place. The hexagonal cross-section is a particularly preferred shape.

The external torque head or tightening head 10 is dimensioned so as to transmit a predetermined torque level, i.e., more than about 45 or 50 inch-pounds and preferably 55 to 65 inch-pounds. The amount of torque which can be applied to the head prior to shearing will depend on the material as well as the cross-sectional area of the neck. Ideally, the head has an external diameter of from about 0.17 to about 0.25 inch, preferably from about 0.18 to about 0.20 inch and has a longitudinal

length of from about 0.07 to about 0.17 inch, preferably from about 0.14 to about 0.16 inch.

For manufacturing purposes, it is convenient if the head 10 has a dimension comparable to the external diameter of the threaded screw portion 20. The torque head 10 is illustrated in the drawings as having a hexagonal external cross-section with a flat-to-flat measurement of about 0.12 to 0.25 inch and more specifically from about 0.14 to about 0.18 inch and with a point-to-point measurement of about 0.12 to about 0.25 inch with a preferred measurement of about 0.16 to about 0.19 inch.

The threaded portion 20 has a longitudinal length of from about 0.1 to about 0.25, and more specifically about 0.18 to about 0.20.

The threaded portion 20 has an external outer diameter of about 0.19 inch, a minor diameter of about 0.15 inch, and a thread pitch of about 28 to about 36, e.g., 32, threads per inch. The thread configuration is a standard, V-shaped thread. The screw portion 20 terminates in a bevel portion 25 which forms an angle of from about 40° to about 50° with respect to the longitudinal axis of the set screw. The screw portion includes a high-compression end 27 which has a rough surface. As shown, the high-compression surface 25 includes a raised diamond knurl with a pitch of about 0.025 inch to increase the compressive grip on the rod. As illustrated, the high-compression surface 27 is circular with a diameter of from about 0.08 to about 0.12 inch. The beveled edge has a longitudinal length of from about 0.03 to about 0.06 inch, and preferably about 0.04 to about 0.05 inch.

In accordance with the invention, a torque-limiting area 30 is provided to limit the application of tightening torque in order to protect the threaded area 20. More specifically, the torque-limiting area 30 comprises a necked portion having a longitudinal length of about 0.03 to about 0.05 inch and having a groove or radiused area which is designed to cause the torque

applicator head 10 to shear at a predetermined load which is between 50 and 70 inch-pounds, preferably from 54 to 64 inch-pounds, in order to eliminate the need for a torque wrench to measure the tightening. Further, the necked area 30 is intended to shear evenly, i.e., in a way which will prevent an uneven break which could inhibit the insertion of a removal tool into the set screw or leave a jagged surface which could cause irritation to the patient.

In conjunction with the necked area 30, the torque head has an internal bore 35 which extends through the necked area 30 and which has a diameter to provide a residual cross-section of the set screw in the necked area to provide the predetermined load limit. For example, a suitable wall thickness is from about 0.015 to about 0.02 inch with an external diameter sized similarly to the minor diameter of the thread.

The threaded set screw portion includes an internal torque opening 50, such as a hexagonal bore. The internal torque applicator opening 50 is designed to allow loosening torques up to approximately 50 inch-pounds which is sufficient for the tightening torques which can be achieved for the present invention. By "internal torque opening" it is meant that the set screw has an opening which permits the internal application of a loosening torque. The internal opening 50 is intended to allow the application of a loosening torque that is approximately two-thirds of the tightening torque. The internal opening 50 of the torque head is illustrated as having a diameter slightly larger than the point-to-point distance of the hexagonal opening which can be achieved by manufacturing the set screw with a hexagonal opening which is subsequently drilled at a longitudinal depth through the necked portion in order to increase and make radially uniform the opening in the applicator.

The set screw of the present invention is illustrated in Figure 5 in a rod anchor 60 with the

applicator head still in place, and in Figure 6 with a sheared applicator head. During surgery, however, the set screw would be loaded into the socket of a screwdriver which would receive the applicator head in order to install the set screw in its location. The instrument would be designed to grasp and hold the sheared head in order to avoid the head dropping into a wound. Further, the instrument may include means such as a spring-loaded C-clip which holds the set screw and which has a cavity into which the sheared head is transferred by a subsequently installed torque head of a subsequent set screw.

The surgeon can remove the set screw by seating a driver tool into the internal torque applicator opening, i.e., the internal hex, and reversing the direction of torque. The current invention increases the ease of removal of the set screw since the necked area inhibits the possibility of overtightening the screws and stripping the threads of the set screw.

The set screw is made of a sufficiently hard biocompatible material such as, for example, hardened, surgical-grade stainless steel, e.g., 22-13-5 stainless steel. Other appropriate materials such as titanium or biocompatible plastics or composites may be used with the appropriate revision to the prescribed predetermined load limit and rates of compression.

A static axial slip test was performed using a closed rod anchor with both annealed and unannealed rods and shear head set screws in accordance with the invention. The amount of load applied to cause 0.012 inch of axial slip was measured for four samples each of annealed rods and unannealed rods.

For the annealed rods, the mean axial slip value was 376.4 pounds; the mean value of shear-off torque was 59 inch-pounds with a S.D. of 2 inch-pounds; and the set screw removal torque mean value was 42 inch-pounds with a S.D. of 4 inch-pounds. (This value was measured after the axial slip test and may have been effected by that test.)

For the unannealed rods, the axial slip failure load mean value was 342.5 pounds; the mean shear-off torque for these samples was 61 inch-pounds with a S.D. of 1 inch-pound; and the set screw removal torque mean value after axial slip was 35 inch-pounds with an S.D. of 2 inch-pounds.

The testing revealed that the set screw of the invention with the rod anchor achieves a desirable compressive loading on the rod by achieving satisfactory tightening and loosening torque values.

While in accordance with the patent statutes the best mode and preferred embodiment has been set forth, the scope of the invention is not limited thereto, but rather by the scope of the attached claims.

WHAT IS CLAIMED IS:

1. In accordance with the invention, a spinal implant set screw is provided having an external torque head joined by a torque-limiting area to a screw member having an internal torque opening.

2. A spinal implant set screw as set forth in Claim 1, wherein said torque-limiting area comprises a necked portion.

3. A spinal implant set screw as set forth in Claim 1, wherein said torque-limiting area further includes an internal opening.

4. A spinal implant set screw as set forth in Claim 1, wherein said torque-limiting area has a reduced cross-sectional area.

5. A spinal implant set screw as set forth in Claim 1, wherein said internal torque opening comprises a hexagonal opening.

6. A spinal implant set screw as set forth in Claim 4, wherein said screw member has a high-compression surface.

7. A spinal implant set screw as set forth in Claim 6, wherein said high-compression surface is a knurled surface.

8. A spinal implant set screw as set forth in Claim 7, wherein said screw member has a bevel and a lateral surface with said knurled surface.

9. A spinal implant set screw as set forth in Claim 8, wherein said external torque head comprises a head having an external hexagonal cross-section.

10. An orthopedic set screw having a torque head joined by a torque-limiting area to an externally threaded screw member, said torque-limiting area being an area of reduced external diameter and including a central opening, said screw member including an internal torque applicator opening and including an external, high-compression, rod-contacting surface.

11. An orthopedic set screw as set forth in Claim 10, which comprises a biocompatible, surgical-grade metal.

12. An orthopedic set screw as set forth in Claim 11, wherein said applicator head shears at said torque-limiting area at a torque of from about 54 to about 64 inch-pounds and said internal torque applicator area allows a loosening torque of up to about 50 inch-pounds.

13. Am orthopedic set screw as set forth in Claim 12, wherein said torque applicator head has an external cross-sectional hexagonal shape and said torque applicator opening has an internal hexagon cross-section.

14. A surgical screw having a longitudinal axis and a first threaded portion having a knurled terminal surface, and an axially aligned second portion with a hexagonal-shaped external configuration, said screw having an opening along said longitudinal axis which is hexagonal-shaped in at least said first threaded portion.

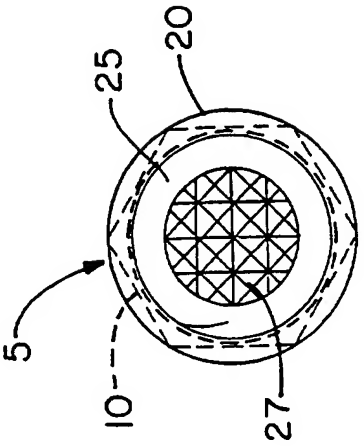


FIG.-3

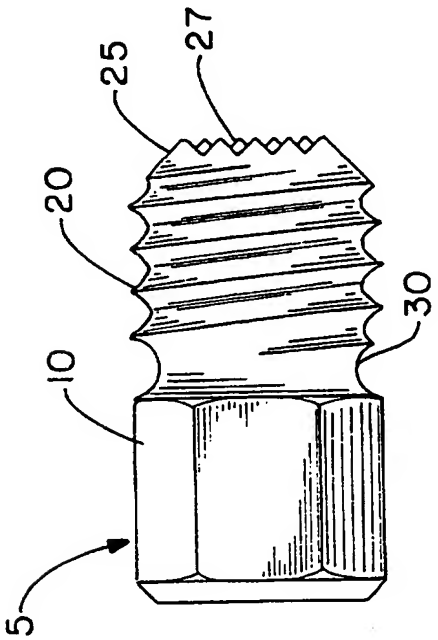


FIG.-1

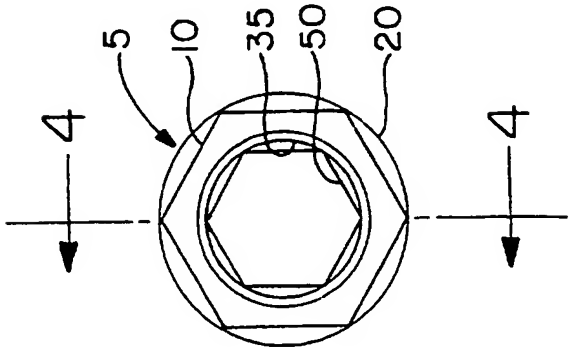


FIG.-2

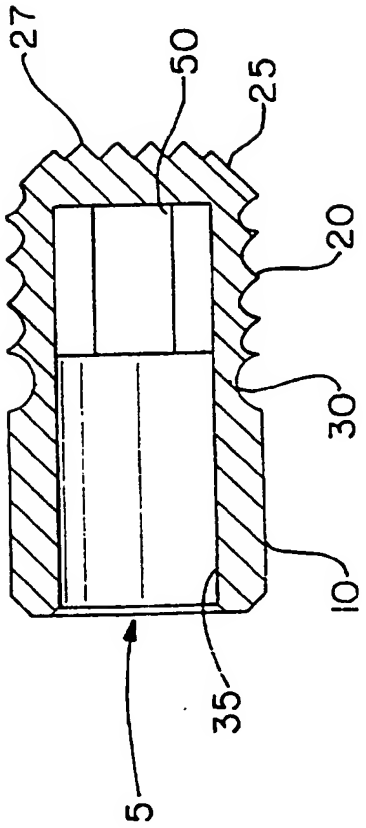


FIG.-4

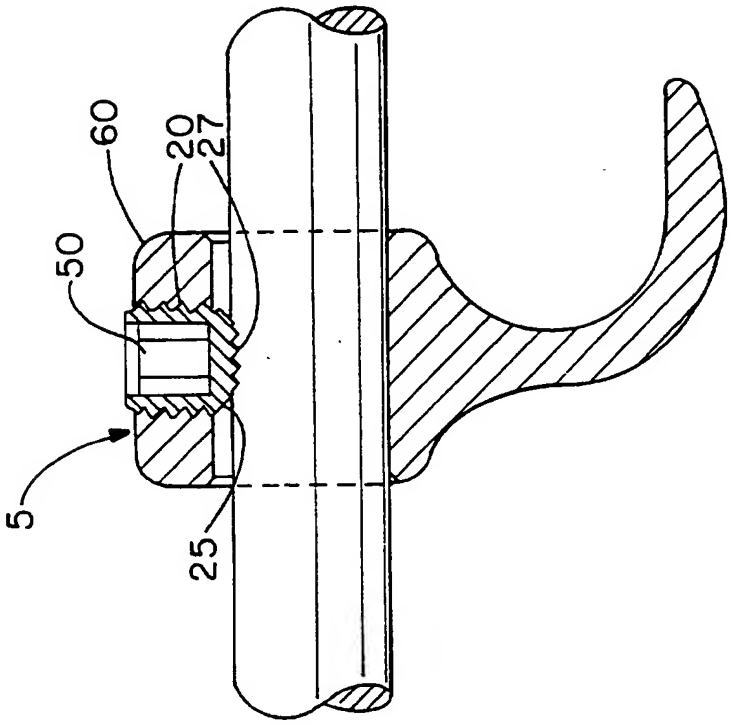


FIG.-6

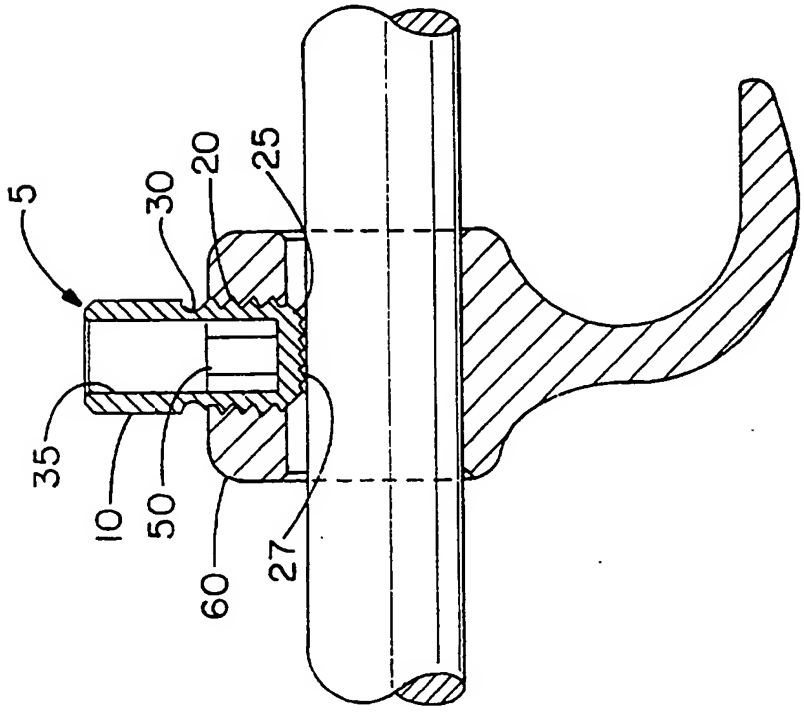


FIG.-5

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US96/17283

A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) :A61B 17/56
US CL :606/61, 72, 73

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 411/1, 5, 393, 403; 606/61, 72, 73

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 3,812,757 A (REILAND) 28 May 1974, Figs. 7 and 9-11.	1-4, 6, 9, 10
---		---
Y		5, 7, 8, 11-14
Y	FR 2467312 A (LAMBERT) 08 May 1981, Fig. 1.	5, 13, 14
Y	US 4,764,068 A (CRISPELL) 16 August 1988, Fig. 7.	7, 8, 14
Y,P	US 5,507,747 A (YUAN et al) 16 April 1996, col. 1, lines 57-61.	11
A	US 4,506,917 A (HANSEN ARNE) 26 March 1985, Fig. 1.	1-14

[X] Further documents are listed in the continuation of Box C. [ ] See patent family annex.

*	Special categories of cited documents:	"T"	later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"A"	document defining the general state of the art which is not considered to be of particular relevance	"X"	document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"E"	earlier document published on or after the international filing date	"Y"	document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"L"	document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"&"	document member of the same patent family
"O"	document referring to an oral disclosure, use, exhibition or other means		
"P"	document published prior to the international filing date but later than the priority date claimed		

Date of the actual completion of the international search 12 DECEMBER 1996	Date of mailing of the international search report 08 JAN 1997
Name and mailing address of the ISA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231	Authorized officer JULIAN W. WOO

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US96/17283

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 4,492,500 A (EWING) 08 January 1985, Fig. 3.	1-14
A	US 5,364,400 A (REGO, JR. et al) 15 November 1994, Fig. 7.	1-14
A,P	US 5,499,892 A (REED) 19 March 1996, Fig. 1.	1-14
A	GB 203508 A (HINDLE et al) 13 September 1923, Fig. 1.	1-14
A	DE 3738409 A (MEYER) 24 May 1989, Fig. 2.	1-14